

Express Mail Label No. EM015925413US

11-23-07

(2)

PTO/SB/21 (09-04)

Approved for use through 07/31/2006. OMB 0651-0031  
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

<b>TRANSMITTAL FORM</b>  (to be used for all correspondence after initial filing)	Application Number	10/570,117
	Filing Date	February 28, 2006
	First Named Inventor	Joerg Heyer
	Art Unit	Not Yet Assigned
	Examiner Name	Not Yet Assigned
Total Number of Pages in This Submission	Attorney Docket Number	GEN/022

ENCLOSURES (Check all that apply)		
<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Information Disclosure Statement <input checked="" type="checkbox"/> PTO/SB/08a (in duplicate) With 21 cited references <input type="checkbox"/> Response to Missing Parts/ Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____ <input type="checkbox"/> Landscape Table on CD	<input type="checkbox"/> After Allowance Communication to TC <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below):  -- Postcard
<b>Remarks</b> The Director is hereby authorized to charge payment of any additional fees required in connection with this Information Disclosure Statement to Deposit Account No. 06-1075, Order No. <u>001581-0211</u> . A duplicate copy of this letter is transmitted herewith.		

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT			
Firm Name	Ropes & Gray LLP (Customer No. 1473)		
Signature	<i>Connie Wong</i>		
Printed name	Connie Wong		
Date	November 20, 2007	Reg. No.	L0104

EXPRESS MAIL CERTIFICATION (EM015925413US)			
I hereby certify that this paper/fee is being deposited with the United States Postal Service "EXPRESS MAIL POST OFFICE TO ADDRESSEE" service under 37 C.F.R. 1.10 on the date indicated above and is addressed to the Mail Stop Amendment, Hon. Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.			
Signature	<i>Sarah Schlie</i>		
Typed or printed name	Sarah Schlie	Date	November 20, 2007

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

American LegalNet, Inc.  
www.USCourtForms.com



Express Mail Label No. EM015925413US

PTO/SB/21 (09-04)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

**TRANSMITTAL  
FORM**

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

Application Number	10/570,117
Filing Date	February 28, 2006
First Named Inventor	Joerg Heyer
Art Unit	Not Yet Assigned
Examiner Name	Not Yet Assigned
Attorney Docket Number	GEN/022

**ENCLOSURES (Check all that apply)**

<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Information Disclosure Statement <input checked="" type="checkbox"/> PTO/SB/08a (in duplicate) With 21 cited references <input type="checkbox"/> Response to Missing Parts/ Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____ <input type="checkbox"/> Landscape Table on CD	<input type="checkbox"/> After Allowance Communication to TC <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below):  -- Postcard
<b>Remarks</b> The Director is hereby authorized to charge payment of any additional fees required in connection with this Information Disclosure Statement to Deposit Account No. 06-1075, Order No. 001581-0211. A duplicate copy of this letter is transmitted herewith.		

**SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT**

Firm Name	Ropes & Gray LLP (Customer No. 1473)		
Signature	<i>Connie Wong</i>		
Printed name	Connie Wong		
Date	November 20, 2007	Reg. No.	L0104

**EXPRESS MAIL CERTIFICATION (EM015925413US)**

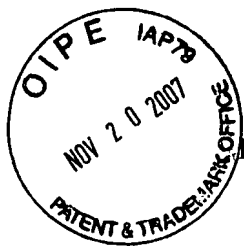
I hereby certify that this paper/fee is being deposited with the United States Postal Service "EXPRESS MAIL POST OFFICE TO ADDRESSEE" service under 37 C.F.R. 1.10 on the date indicated above and is addressed to the Mail Stop Amendment, Hon. Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Signature	<i>Sarah Schlie</i>		
Typed or printed name	Sarah Schlie	Date	November 20, 2007

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

American LegalNet, Inc.  
www.USCourtForms.com



Express Mail Label No. EM015925413US

Attorney Docket No.: GEN/022

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Joerg Heyer et al.  
Application No. : 10/570,117 Confirmation No.: 8044  
Filed : February 28, 2006  
For : TUMOR-SPECIFIC EXPRESSION OF REPORTER GENES  
Group Art Unit : Not Yet Assigned  
Examiner : Not Yet Assigned

New York, New York  
November 20, 2007

**Mail Stop: Amendment**  
Hon. Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

Pursuant to 37 C.F.R. §§ 1.56 and 1.97, applicants, through their attorneys, make of record the documents listed below. Pursuant to 37 C.F.R. § 1.98(a)(2)(ii), applicants have not provided paper copies of the U.S. Patent Documents, which are listed on the accompanying Form PTO/SB/08A (submitted in duplicate).

Applicants respectfully request that the documents listed below and on Form PTO/SB/08A be (1) fully considered by the Examiner prior to issuance of any patent from this application and (2) printed on any patent issuing from this application.

Applicants also request that a copy of the enclosed Form PTO/SB/08A duly initialed by the Examiner be forwarded to the undersigned with the next communication.

#### Other Documents

Bao, R., *et al.*, "Activation of cancer-specific gene expression by the survivin promoter," *J. of the National Cancer Inst.* 94:522-528 (2002).

Chatterjee, B., *et al.*, "BMP regulation of the mouse connexin43 promoter in osteoblastic cells and embryos," *Cell Communication and Adhesion* 10:37-50 (2003).

Contag, *et al.*, "Advances in *in vivo* bioluminescence imaging of gene expression," *Annual Review of Biomed. Eng.* 4:235-260 (2002).

Coralli, C., *et al.*, "Limitations of the reporter green fluorescent protein under simulated tumor conditions," *Cancer Research* 61:4784-4790 (2001).

Elbashir *et al.*, "Analysis of gene function in somatic mammalian cells using small interfering RNAs," *Methods* 26:199-213 (2002).

Giles *et al.*, "Caught up in a Wnt storm: Wnt signaling in cancer," *Biochimica et Biophysica Acta* 1653:1-24 (2003).

Hannon, "RNA interference," *Nature* 418:244-251 (2002).

Jacks *et al.*, "Effects of an Rb mutation in the mouse," *Nature* 359:295-300 (1992).

Kim *et al.*, "Survivin and molecular pathogenesis of colorectal cancer," *Lancet* 362:205-209 (2003).

Massuda, E.S., *et al.*, "Regulated expression of the diphtheria toxin A chain by a tumor-specific chimeric transcription factor results in selective toxicity for alveolar rhabdomyosarcoma cells," *Proc. Nat'l. Acad. Sci.* 94:14701-14706 (1997).

McManus, M.T., *et al.*, "Gene silencing in mammals by small interfering RNAs," *Nature Reviews* 3:737-747 (2002).

Staal, F.J.T., *et al.*, "Tcf-1-mediated transcription in T lymphocytes: differential role for glycogen synthase kinase-3 in fibroblasts and T cells," *Int'l Immunology* 11:317-323 (1999).

Vooijs *et al.*, "Noninvasive imaging of spontaneous retinoblastoma pathway-dependent tumors in mice," *Cancer Res.* 62(6):1862-1867 (2002).

Young, M.R. *et al.*, "Transgenic mice demonstrate AP-1 (activator protein-1) transactivation is required for tumor promotion," *Proc. Natl. Acad. Sci.* 96:9827-9832 (1999).

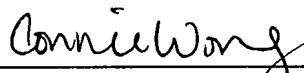
Zhong, S., *et al.*, "Organ-specific activation of activator protein-1 in transgenic mice by 12-O-tetradecanoylphorbol-13-acetate with different administration methods," *Cancer Research* 61:4084-4091 (2001).

Zhong, S.P., *et al.*, "Organ-specific distribution of AP-1 in AP-1 luciferase transgenic mice during the maturation process," *Am. J. Physiol Regul Integr Comp Physiol* 280:R376-R381 (2001).

This Statement is being submitted more than three months from the application filing date but before the mailing date of the first Office Action on the merits. In accordance with 37 C.F.R. § 1.97, submission of this Statement requires no fee.

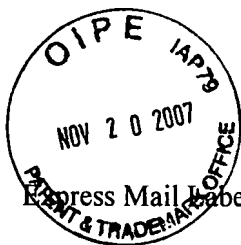
The Director, however, is hereby authorized to charge payment of any fees required in connection with this Information Disclosure Statement to Deposit Account No. 06-1075, Order No. 001581-0211.

Respectfully submitted,



---

Jane T. Gunnison (Reg. No. 38,479)  
Connie Wong (Reg. No. L0104)  
Attorneys for Applicants  
ROPES & GRAY LLP  
Customer No. 1473  
1211 Avenue of the Americas  
New York, New York 10036  
Tel.: (212) 596-9000  
Fax.: (212) 596-9090



Express Mail Label No. EM015925413US

Attorney Docket No.: GEN/022

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Joerg Heyer et al.  
Application No. : 10/570,117 Confirmation No.: 8044  
Filed : February 28, 2006  
For : TUMOR-SPECIFIC EXPRESSION OF REPORTER GENES  
Group Art Unit : Not Yet Assigned  
Examiner : Not Yet Assigned

New York, New York  
November 20, 2007

**Mail Stop: Amendment**  
Hon. Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

Pursuant to 37 C.F.R. §§ 1.56 and 1.97, applicants, through their attorneys, make of record the documents listed below. Pursuant to 37 C.F.R. § 1.98(a)(2)(ii), applicants have not provided paper copies of the U.S. Patent Documents, which are listed on the accompanying Form PTO/SB/08A (submitted in duplicate).

Applicants respectfully request that the documents listed below and on Form PTO/SB/08A be (1) fully considered by the Examiner prior to issuance of any patent from this application and (2) printed on any patent issuing from this application.

Applicants also request that a copy of the enclosed Form PTO/SB/08A duly initialed by the Examiner be forwarded to the undersigned with the next communication.

#### Other Documents

Bao, R., *et al.*, "Activation of cancer-specific gene expression by the survivin promoter," *J. of the National Cancer Inst.* 94:522-528 (2002).

Chatterjee, B., *et al.*, "BMP regulation of the mouse connexin43 promoter in osteoblastic cells and embryos," *Cell Communication and Adhesion* 10:37-50 (2003).

Contag, *et al.*, "Advances in *in vivo* bioluminescence imaging of gene expression," *Annual Review of Biomed. Eng.* 4:235-260 (2002).

Coralli, C., *et al.*, "Limitations of the reporter green fluorescent protein under simulated tumor conditions," *Cancer Research* 61:4784-4790 (2001).

Elbashir *et al.*, "Analysis of gene function in somatic mammalian cells using small interfering RNAs," *Methods* 26:199-213 (2002).

Giles *et al.*, "Caught up in a Wnt storm: Wnt signaling in cancer," *Biochimica et Biophysica Acta* 1653:1-24 (2003).

Hannon, "RNA interference," *Nature* 418:244-251 (2002).

Jacks *et al.*, "Effects of an Rb mutation in the mouse," *Nature* 359:295-300 (1992).

Kim *et al.*, "Survivin and molecular pathogenesis of colorectal cancer," *Lancet* 362:205-209 (2003).

Massuda, E.S., *et al.*, "Regulated expression of the diphtheria toxin A chain by a tumor-specific chimeric transcription factor results in selective toxicity for alveolar rhabdomyosarcoma cells," *Proc. Nat'l. Acad. Sci.* 94:14701-14706 (1997).

McManus, M.T., *et al.*, "Gene silencing in mammals by small interfering RNAs," *Nature Reviews* 3:737-747 (2002).

Staal, F.J.T., *et al.*, "Tcf-1-mediated transcription in T lymphocytes: differential role for glycogen synthase kinase-3 in fibroblasts and T cells," *Int'l Immunology* 11:317-323 (1999).

Vooijs *et al.*, "Noninvasive imaging of spontaneous retinoblastoma pathway-dependent tumors in mice," *Cancer Res.* 62(6):1862-1867 (2002).

Young, M.R. *et al.*, "Transgenic mice demonstrate AP-1 (activator protein-1) transactivation is required for tumor promotion," *Proc. Natl. Acad. Sci.* 96:9827-9832 (1999).

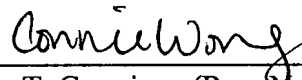
Zhong, S., *et al.*, "Organ-specific activation of activator protein-1 in transgenic mice by 12-O-tetradecanoylphorbol-13-acetate with different administration methods," *Cancer Research* 61:4084-4091 (2001).

Zhong, S.P., *et al.*, "Organ-specific distribution of AP-1 in AP-1 luciferase transgenic mice during the maturation process," *Am. J. Physiol Regul Integr Comp Physiol* 280:R376-R381 (2001).

This Statement is being submitted more than three months from the application filing date but before the mailing date of the first Office Action on the merits. In accordance with 37 C.F.R. § 1.97, submission of this Statement requires no fee.

The Director, however, is hereby authorized to charge payment of any fees required in connection with this Information Disclosure Statement to Deposit Account No. 06-1075, Order No. 001581-0211.

Respectfully submitted,



---

Jane T. Gunnison (Reg. No. 38,479)  
Connie Wong (Reg. No. L0104)  
Attorneys for Applicants  
ROPES & GRAY LLP  
Customer No. 1473  
1211 Avenue of the Americas  
New York, New York 10036  
Tel.: (212) 596-9000  
Fax.: (212) 596-9090